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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/143,143	08/28/1998	STEPHEN R. ASH	37011-6	3135

7590 11/16/2001

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/16/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/143,143

Applicant(s)

ASH

Examiner

Pak, J.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 17, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-29, 31-37, 39-41, 44, and 46-66 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-29, 31-37, 39-41, 44, and 46-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Art Unit: 1616

Claims 24-29, 31-37, 39-41, 44 and 46-66 are pending in this application.

Applicant is advised of the following allowable subject matter: the claimed subject matter, as presently pending, wherein (i) the iron complex is **not** iron gluconate, and/or (ii) iron complex is **not** iron-dextran with a molecular weight of less than 50,000. The claims will continue to be examined to the extent that they read on iron gluconate and iron-dextran with a molecular weight of less than 50,000.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-29, 31-37, 39-41, 44 and 46-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Bellini et al. in view of the acknowledged prior art and Martindale The Extra Pharmacopoeia for the reasons first fully set forth in the Office Action of Paper No. 11 (5/18/00), pages 3-5.

Background information for reinstating this ground of rejection at this time is in order. This ground of rejection was replaced in favor of the rejection set forth in Paper No. 16 (2/14/01) because of applicant's erroneous assertion in Paper No. 13, page 14 (11/21/00). There, applicant argued that his specification admission that intraperitoneal delivery of iron dextran is known is predated by applicant's provisional application. Applicant's argument was accepted at the time,

Art Unit: 1616

and another reference was applied to supplement the rejection rationale. However, it now appears that applicant's specification admission is indeed applicable here, since it was actually known prior to applicant's invention to deliver iron dextran by intraperitoneal route. See for example Medline accession numbers 70113694 and 76201043¹. It was applicant's mistaken argument that misled the Examiner and it was applicant's mistaken argument that led to not maintaining this now-reinstated ground of rejection.

In summary of the reinstated ground of rejection, Bellini et al. clearly disclose concentrated and diluted peritoneal dialysis solutions that contain electrolytes, gluconate salts such as iron gluconate and glucose and the ordinary skilled artisan has been taught that iron dextran can be administered intraperitoneally. The ordinary skilled artisan in this field is a highly educated and trained medical professional responsible for critical care of dialysis patients, who would not blindly formulate dialysis solution ingredients to induce a toxic reaction. Upon having been taught that iron gluconate and iron dextran may be given to dialysis patients by the intraperitoneal route, it would have been through routine experimentation that he/she would have arrived at the appropriate concentrations of electrolytes and iron gluconate or iron dextran (with a molecular weight of less than 50,000) suitable for a dialysis patient in need of iron supplementation, as claimed.

¹ Note, these references are not being cited as prior art in this ground of rejection. They are merely shown here to prove that applicant's specification admission was accurate and applicable against the claimed invention and applicant's argument in page 14 of Paper No. 13 (11/21/00) was erroneous.

Art Unit: 1616


For these reasons, the claims are rejected again. This Office Action is being made FINAL in view of the background facts regarding the prosecution of this case and the repeated same ground of rejection. Applicant is invited to telephone the Examiner to further advance the prosecution of this application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


JOHN PAK
PRIMARY EXAMINER
GROUP 1616